IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: J. Kyle Mathews, M.D.)

Pending in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, is the plaintiffs' General Motion to Exclude Certain Opinions and Testimony of J. Kyle Mathews, M.D. [ECF No. 4570]. The motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in part** and **RESERVED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and

(1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness"

> standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Mathews is a practicing urogynecologist who is board-certified in both Obstetrics and Gynecology as well as Female Pelvic Medicine and Reconstructive Surgery. He has performed thousands of surgeries to treat POP. He is a Director of Female Pelvic Medicine and Reconstructive Surgery at Medical Center Plano/Medical City Frisco and at Plano Urogynecology Associates. Dr. Mathews has also served as a clinical preceptor, clinical investigator, and anatomical laboratory instructor for several medical device companies, in which role he has instructed other surgeons on the proper use and placement of slings and mesh products.

A. Properties of Polypropylene and Product Design

First, the plaintiffs argue that Dr. Mathews should not be permitted to offer opinions on the properties of polypropylene and certain design features of the Avaulta and Align products. Specifically, Dr. Mathews opines that polypropylene does not degrade inside the body, and that the mean mesh pore size used in Bard's products is intended to reduce inflammation, which makes them "ideal" for the treatment of SUI. The plaintiffs assert that Dr. Mathews's opinions are unreliable because they are based solely on his personal clinical experience and because he failed to sufficiently consider scientific literature that was contrary to his view.

Dr. Mathews's opinion that polypropylene does not degrade inside the body is based on his clinical experience, during which he did not observe evidence of

degradation, and upon his review of the relevant medical and scientific literature. Similarly, Dr. Mathews's opinion that the design of the Avaulta and Align make them "ideal" for the treatment of SUI is based on his personal observations of how these products react to implantation inside the body, and their effectiveness at treating SUI.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g.*, *Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion

because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Mathews has based his opinions on his extensive clinical experience and a review of the medical and scientific literature; in the abstract, these are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Mathews did not observe evidence of mesh degradation because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Mathews reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Mathews's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties or product design characteristics based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

B. Material Safety Data Sheet ("MSDS")

Second, plaintiffs object to Dr. Mathews's opinions regarding the MSDS for Marlex polypropylene resin—specifically, that Dr. Mathews does not utilize MSDSs in his practice, and that there is no credible scientific evidence supporting the medical application caution. Dr. Mathews's opinions on his and other doctors' experience with the MSDS for raw polypropylene pellets is not relevant or helpful to the jury. The pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials Bard uses to manufacture its medical devices. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 577 (S.D. W. Va. 2014) (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury"). Nevertheless, I acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Mathews's MSDS opinions for trial.

C. Adequacy of Warnings

Third, plaintiffs challenge the reliability of Dr. Mathews's opinions about the adequacy of the Avaulta and Align Instructions for Use ("IFU") and his qualifications to offer such opinions. The two arguments are intertwined, and I treat them here together. The plaintiffs argue that Dr. Mathews has no knowledge or experience working on or drafting IFUs. In response, Bard argues that "Dr. Mathews has used and received expert training with regard to both the Avaulta and the Align products," and that he has reviewed numerous IFUs. Bard's Br. in Opp'n to Pls.' *Daubert* Mot. to Exclude Certain Ops. & Test. of J. Kyle Mathews, M.D. 14–15 [ECF No. 4628]. I

have repeatedly ruled that, without additional expertise in the specific area of product warnings, a doctor such as Dr. Mathews is not qualified to opine that a product warning was adequate merely because it included risks he observed in his own practice. Neither Dr. Mathews's training on the Avaulta and Align products nor his review of various IFUs provide him with the expertise necessary to opine on the adequacy of the warnings contained on Bard's mesh products. Accordingly, the plaintiffs' motion is **GRANTED** on this issue, and Dr. Mathews's opinions related to product labeling are **EXCLUDED**.

D. FDA Findings

Fourth, plaintiffs seek to exclude Dr. Mathews's opinion regarding the FDA's Public Health Notifications addressing transvaginal mesh. In July of 2011, the FDA issued an update to its 2008 Public Health Notification, stating that serious complications associated with transvaginal mesh were "not rare," and reporting a five-fold increase in adverse events since 2008. *See* Mathews Report 7 [ECF No. 4570-1]. In his expert report, Dr. Mathews opines that "[t]his statement is not statistically supported and is an error by the FDA." *Id.* at 8. Plaintiffs argue that this opinion is not relevant to the issues in these products liability cases.

Throughout these MDLs, I have repeatedly excluded evidence relating to the FDA 510(k) clearance process—a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prods. Liab. Litig.*, 81 F.3d 913, 921–23 (4th Cir. Jan. 14, 2016) (upholding the determination that the probative value of 510(k)-related evidence was substantially outweighed by its

possible prejudicial impact under Rule 403). Because the 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.").

Here, the opinion challenged by the plaintiffs does not directly relate to the 510(k) process or regulatory compliance. Instead, the challenged opinion addresses a statement issued by the FDA on the complication rates of transvaginal mesh procedures, which Dr. Mathews believes to be erroneous. The plaintiffs argue that this opinion is an attempt by Bard to "backdoor" this court's previous rulings on the 510(k) process and introduce FDA-related testimony.

Although Dr. Mathews's opinion on the validity of the FDA's July 2011 Public Health Notification does not directly relate to the 510(k) process or regulatory compliance, I find that it is irrelevant to the issues in these MDLs. Accordingly, Dr. Mathews's opinion on the Public Health Notifications is **EXCLUDED**. The plaintiffs' motion on this point is **GRANTED**.

E. Position Statements

Finally, the plaintiffs seek to exclude Dr. Mathews's opinions relating to position statements issued by the American Urogynecology Society ("AUGS") and other similar associations. As previously noted by the court, position statements themselves are not expert opinions. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 731 (S.D. W. Va. 2014). Bard contends that Dr. Mathews does not offer any opinions on

the propriety of the position statements themselves, but merely relied on them to support his position on the biocompatibility of transvaginal mesh and midurethral slings. *See* Bard's Br. in Opp'n 19.

As I have previously indicated in these MDLs, I will not address the admissibility of such testimony at this time. Accordingly, I **RESERVE** ruling on the admissibility of this testimony for trial. *See, e.g.*, *Flandro v. Bos. Sci. Corp.*, No. 2:13-cv-17027, 2016 WL 3282734, at *14 (S.D. W. Va. June 14, 2016); *Griffin v. Bos. Sci. Corp.*, No. 2:13-cv-11876, 2016 WL 3031700, at *18 (S.D. W. Va. May 25, 2016).

IV. Conclusion

To summarize, the plaintiffs' General Motion to Exclude Certain Opinions and Testimony of J. Kyle Mathews, M.D. [ECF No. 4570] is **GRANTED in part** and **RESERVED in part** consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 4, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.